



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Biogenix, LLC
% Ms. Elaine Duncan
President
Paladin Medical, Incorporated
P.O. Box 560
Stillwater, Minnesota 55082

January 15, 2015

Re: K142828
Trade/Device Name: osteoSPAN Morpheus
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: December 18, 2014
Received: December 19, 2014

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142828

Device Name

osteoSPAN Morpheus

Indications for Use (Describe)

BIOGENNIX osteoSPAN Morpheus is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, posterolateral spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides bone void filler that resorbs and is replaced with bone during the healing process. When used in the posterolateral spine, osteoSPAN Morpheus must be used as a bone graft extender, mixed in a one to one ratio with autogenous bone graft.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(K) SUMMARY

Submitted on behalf of:

Company Name: **BIOGENNIX, LLC**
Address: **18011 Sky Park Circle, Ste M
Irvine, CA 92614**

Telephone: **949-253-0094**
Fax: **949-266-5800**

by: Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
Telephone: 715-549-6035
Fax: 715-549-5380

CONTACT PERSON: Elaine Duncan

DATE PREPARED: January 14, 2015

TRADE NAME: osteoSPAN Morpheus
COMMON NAME: bone void filler
CLASSIFICATION NAME: 21 CFR 888.3045;
Resorbable calcium salt bone void-filler device
PRO CODE: MQV

DESCRIPTION of the DEVICE:

osteoSPAN Morpheus is a moldable, osteoconductive bone graft substitute composed of 1-2mm osteoSPAN granules suspended in a resorbable organic binder. The osteoSPAN granules used in osteoSPAN Morpheus are a composite of calcium carbonate with a thin calcium phosphate layer, in the form of hydroxyapatite, coating on all the surfaces of the interconnected porosity. The interconnected pores are approximately 500 microns in diameter and occupy approximately 65% of the volume. The biocompatible, organic binder used in osteoSPAN Morpheus facilitates placement and containment of the implant and is rapidly resorbed in-situ, leaving behind the osteoSPAN granules without affecting their osteoconductive or resorbable properties.

This submission expands the indication for use to include posterolateral spine.

INDICATIONS FOR USE:

BIOGENNIX osteoSPAN Morpheus is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, posterolateral spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides bone void

510(k) Summary-Continued

filler that resorbs and is replaced with bone during the healing process. When used in the posterolateral spine, osteoSPAN Morpheus must be used as a bone graft extender, mixed in a one to one ratio with autogenous bone graft.

SUMMARY of HOW TECHNOLOGICAL CHARACTERISTICS COMPARE:

The subject device is IDENTICAL to osteoSPAN Morpheus cleared under K132377, except for an expanded indication for use in posterolateral spine fusion and updated instructions for use which now include guidelines for use in posterolateral spine fusion. The osteoSPAN predicate device (K093342) is the primary component of osteoSPAN Morpheus and has not been altered in any way; therefore, both devices have identical osteoconductive potential.

Product	Calcium Salt	Granule Size	Porosity	Polymer Binder	Osteo-conductive
osteoSPAN Morpheus K132377	Calcium carbonate/calcium phosphate composite	1-2mm	65%	Yes	Yes
osteoSPAN (K093342)	Calcium carbonate/calcium phosphate composite	1-4mm	65%	No	Yes

SUBSTANTIALLY EQUIVALENT TO:

The contents of this submission have demonstrated that osteoSPAN Morpheus is substantially equivalent to OsteoSPAN when used as a bone graft extender in posterolateral spine cleared under K093342 (primary predicate); and is identical to the predicate osteoSPAN Morpheus cleared under K132377. This submission does not change any aspect of the osteoSPAN Morpheus. This submission only adds the additional indication for use for osteoSPAN Morpheus.

CONCLUSION FROM TESTING:

Supplementary preclinical performance testing confirmed that osteoSPAN Morpheus has substantially equivalent bone ingrowth, tissue reaction, mechanical strength and residual material as its predicate osteoSPAN when used in a posterolateral spine model; therefore, osteoSPAN Morpheus is substantially equivalent to the predicate device osteoSPAN when used in posterolateral spinal fusion indications.